caBIG Workspace Adopter Project Form

Adopters, please complete this form in advance of the caBIG kickoff meeting and return by e-mail to adamsm@mail.nih.gov. Completed forms will be made available to participants in advance of the meeting to enhance workspace discussions. During our conversations with you, we expressed the aspect of your program that we would like you to develop in the first year of the caBIG pilot; it is this we are asking you to address - here and in your presentation.

1. Sponsoring Cancer Center

Chao Family Comprehensive Cancer Center
University of California, Irvine

2. Workspace

Clinical Trial Management

3. What "data" are you providing as adopters?
    - Data collected for the Chemo Prevention Consortium (from medical records)
        - Open trials in colon, prostate, oral, cervix
        - Pending trials in melanoma
    - Data collected from Hypothesis Driven Investigator Initiated (HDII) trials
        - Treatment
        - Diagnostic/screening
    - Data Safety Monitoring Board (DSMB) reports
        - Adverse Event reports w/ narrative
    - Protocols tracking data
    - Patient registration databases
    - Specimen tracking data and lab endpoints
    - Additional basic science data

4. What are the tools you envision would enhance the use and analysis of this "data"?
    - Currently, the aforementioned data is manually entered and stored in various databases from various vendors (FileMaker Pro, Microsoft Access 97, etc).
    - In collaboration with NCICB, we are in the planning/defining stage of a migrating project, where data will be entered/hosted in an Oracle Clinical environment.
    - To enter data, we need:
        - Remote Data Capture mechanism
        - Better Adverse Event reporting module to sort of "standardize" the formats, vocabularies, etc. of AE reports
        - Distributed patient registration mechanism
    - We need data extraction mechanism:
        - Our statistician group will use SAS to analyze data extracted from Oracle Clinical
    - We need more flexible, sophisticated analytics/reporting tools (not necessarily Oracle Clinical) to:
        - Answer day-to-day clinical questions on demand, (e.g., what patient is on what trial?)
        - Generate patient-specific, patient-centered information on demand

    - Indicate inconsistent data (i.e., highlight exceptions)
- Protocol tracking tool

5. What is your ability to evaluate the tools to be adopted?
We have data managers (~15), lab staff, and a programmer to evaluate adopted tools.

6. How will you provide system integration?
Our immediate need is to figure out how to migrate our production clinical data, from various flavors of databases into a centralized Oracle Clinical environment. Once done, larger system integration can happen from there.

7. How will you provide end-user testing?
Please see 5.

8. How will you provide software validation?
We'll consult with NCICB to learn from their C3DS test plans and experiences. Our statistician group also can validate the data accuracy.

9. What are your plans for interacting with the appropriate workspace developers?
We will actively participate in the on-line user forum, meetings, and we're open to exchange information, knowledge and experiences related in clinical data management with our peer workspace members.